**UNITED STATES DISTRICT COURT**
**NORTHERN DISTRICT OF ILLINOIS**
**EASTERN DIVISION**

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|---|---|
| BAYER HEALTHCARE LLC,<br><br>*Plaintiff*,<br><br>v.<br><br>PFIZER, INC.,<br><br>*Defendant*. | Civil Action No. 1:12-cv-00630<br><br>Hon. Judge Edmond E. Chang<br><br>**FILED UNDER SEAL** |

**PFIZER INC.'S RESPONSES TO BAYER'S STATEMENT OF MATERIAL FACTS IN SUPPORT OF ITS MOTION FOR PARTIAL SUMMARY JUDGMENT DISMISSING PFIZER'S ANTICIPATION AND OBVIOUSNESS DEFENSES**

Pursuant to Local Rule 56.1, Pfizer Inc. ("Pfizer") submits these Responses to "Bayer's Statement Of Facts Supporting Its Cross-Motion For Partial Summary Judgment Dismissing Pfizer's Anticipation And Obviousness Defenses. ("Asserted Facts").

**GENERAL OBJECTIONS**

Pfizer objects to Bayer's inclusion of opinions and arguments in their list of Asserted Facts, including, for example, Asserted Facts 243-51, 255, 258, 263-65, 267, 268, 269, 271, 273, 278, 280, 284, 289. Opinions and arguments do not comply with Local Rule 56.1, which requires a party opposing a motion for summary judgment to set forth the "material facts."

Pfizer further objects to Bayer's inclusion of assertions that are not relevant, much less material, to the issues involved in Bayer's motion for Summary Judgment. Irrelevant assertions likewise do not comply with Local Rule 56.1's requirement that Plaintiffs set forth only "entitle the moving party to a judgment as a matter of law."

**SPECIFIC OBJECTIONS AND RESPONSES**

**ASSERTED FACT #241 RESPONSE:**

Pfizer incorporates by reference its response to Bayer SOF 135. [redacted] Bayer Ex. 90 (D.I. 348) at 77.

**ASSERTED FACT #242 RESPONSE:**

Pfizer incorporates by reference its response to Bayer SOF 136.

**ASSERTED FACT #243 RESPONSE:**

Pfizer objects to this Asserted Fact as vague and ambiguous, irrelevant and immaterial to Bayer's motion, and thus disputed. A person having ordinary skill in the art in 1995 would have believed that a successful treatment of BRD with a fluoroquinolone could be done in a one high dose, single treatment. Pfizer Ex. 10 (D.I. 309), Nov. 19, 2012 Babish Rep. at *e.g.*, ¶¶ 125-426; Pfizer Ex. 11 (D.I. 309), Nov. 19, 2012 Grooms Rep. at 29-61. Additionally, Dr. Grooms testified that [redacted] Bayer Ex. 91 (D.I. 248) at 89-90. Dr. Pollreisz merely testified that relapse is a significant concern for customers of BRD treatments. The cited Dr. Pollreisz testimony has nothing to do with whether a "person of ordinary skill believed that successful treatment of BRD with fluoroquinolones required the antibiotic to remain in the animal's system for a prolonged period in order to eradicate bacteria and prevent relapse."

**ASSERTED FACT #244 RESPONSE:**

Pfizer objects to this Asserted Fact as vague and ambiguous, irrelevant and immaterial to Bayer's motion, and thus disputed. Persons of skill knew that concentration dependency teaches that the amount of dose and not dose frequency was the relevant factor, and that large single

doses as opposed to smaller multiple doses were more effective. *See e.g.,* Pfizer SOF (D.I. 309) 48-64.

**ASSERTED FACT #245 RESPONSE:**

Pfizer objects to this Asserted Fact as vague and ambiguous, irrelevant and immaterial to Bayer's motion, and thus disputed. [redacted]

**ASSERTED FACT #246 RESPONSE:**

Pfizer objects to this Asserted Fact as vague and ambiguous, irrelevant and immaterial to Bayer's motion, and thus disputed. [redacted] Additionally, regarding off-label BRD treatments, the Veterinary Medicine reference teaches that "[o]ne treatment is usually adequate and most economical for most cases…." Pfizer Ex. 18 (D.I. 309) at

PFE-BAY0002970.

**ASSERTED FACT #247 RESPONSE:**

Pfizer objects to this Asserted Fact as vague and ambiguous, and irrelevant and immaterial to Bayer's motion, and thus disputed. Dr. Boettner testified that whether a drug is "long-acting" depends on the context of the particular drug, which Bayer's asserted fact does not provide. For example, Advocin can be considered long-acting. Pfizer Ex. 17 (D.I. 357), Clay Dep. at 64. [redacted]. Ms. Elliott considers Advocin to be long acting relative to a daily injection product. Ex. 31, Elliott Dep. 37.

**ASSERTED FACT #248 RESPONSE:**

Pfizer objects to this Asserted Fact as vague and ambiguous, and irrelevant and immaterial to Bayer's motion, and thus disputed. Ms. Elliott's full testimony was that long-acting is a relative term that would include Baytril 100:

> Q. The single-dose products that were on the market in the second half of the 1990s, you mentioned LA-200 and Micotil. Those are both long-acting products, correct?
>
> A. Yes. Well, again, long-acting is a relative term.
>
> ***
>
> Q. Well, Baytril 100 is not a long-acting product, is it?
>
> A. It's as long as Micotil. It's -- which we just said was a long-acting product.

Ex. 31, Elliot Dep. 174-75.

Ms. Elliott considers Advocin to be long acting relative to a daily injection product. Ex. 31, Elliott Dep. 37. Additionally, the products that were FDA-approved in the mid-1990s are not relevant to the full scope of what was known in the art in the mid-1990s. No fluoroquinolones

were approved for use in treating BRD in the 1990s.

**ASSERTED FACT #249 RESPONSE:**

Pfizer objects to this Asserted Fact as irrelevant and immaterial to Bayer's motion, and thus disputed. [redacted]

Additionally, Pfizer's SOF ¶ 67 itself is not limited to a single reference and is consistent with Dr. Papich's testimony and others. Pfizer Ex. 12 (D.I. 309), Jan. 4, 2013 Babish Rep ¶¶ 40-44; Pfizer Ex. 13 (D.I. 309), Jan. 4, 2013 Grooms Rep. at 17-18.

**ASSERTED FACT #250 RESPONSE:**

Pfizer objects to this Asserted Fact as vague and ambiguous with respect to "largest and most sophisticated," as well as irrelevant and immaterial to Bayer's motion and thus disputed. Additionally, Bayer's citations are not supportive of the asserted fact. [redacted]

**ASSERTED FACT #251 RESPONSE:**

Pfizer's objects to this Asserted Fact as vague and ambiguous, irrelevant and immaterial to Bayer's motion, and thus disputed. Pfizer notes that Bayer has combined what was at least two previous asserted facts and incorporates its previous responses by reference. *See e.g.,* Pfizer

Response to Bayer SOF 125, 127. Pfizer is not in a position to be able to admit or deny the knowledge of Bayer that is described in the asserted fact. Additionally, the citations provided by Bayer do not fully support the asserted fact. [redacted] Pfizer further dispute the use of "long-acting." For example, Advocin can be considered long-acting. Pfizer Ex. 17 (D.I. 357), Clay Dep at 64. There is no bright line between longer acting formulations and other formulations. Pfizer Ex. 12 (D.I. 309), Jan. 4, 2013 Babish Rep. ¶ 6. Ms. Elliott considers Advocin to be long acting relative to a daily injection product. Ex. 31, Elliott Dep. 37.

**ASSERTED FACT #252 RESPONSE:**

Pfizer incorporates by response its response to Bayer SOF 126. Pfizer further disputes the use of "long-acting." For example, Advocin can be considered long-acting. Pfizer Ex. 17 (D.I. 357), Clay Dep. at 64. There is no bright line between longer acting formulations and other formulations. Pfizer Ex. 12 (D.I. 309), Jan. 4, 2013 Babish Rep. ¶ 6. Ms. Elliott considers Advocin to be long acting relative to a daily injection product. Ex. __, Elliott Dep. 37.

**ASSERTED FACT #253 RESPONSE:**

Pfizer incorporates by response its response to Bayer SOF 128. Pfizer further dispute the use of "long-acting." For example, Advocin can be considered long-acting. Pfizer Ex. 17 (D.I. 357), Clay Dep. at 64. There is no bright line between longer acting formulations and other formulations. Pfizer Ex. 12 (D.I. 309), Jan. 4, 2013 Babish Rep. ¶ 6. Ms. Elliott considers Advocin to be long acting relative to a daily injection product. Ex. 31, Elliott Dep. 37.

**ASSERTED FACT #254 RESPONSE:**

Pfizer incorporates by response its response to Bayer SOF 129.

**ASSERTED FACT #255 RESPONSE:**

Pfizer incorporates by response its response to Bayer SOF 130.

**ASSERTED FACT #256 RESPONSE:**

Pfizer incorporates by response its response to Bayer SOF 131.

**ASSERTED FACT #257 RESPONSE:**

Pfizer incorporates by response its response to Bayer SOF 132.

**ASSERTED FACT #258 RESPONSE:**

Pfizer objects to this Asserted Fact as vague and ambiguous, irrelevant and immaterial to Bayer's motion, and thus disputed. There is no nexus between any commercial success by Baytril 100 and the asserted claims. *See e.g.*, Pfizer Ex. 10 (D.I. 309), Nov. 19, 2012 Babish Rep. ¶ 429; Pfizer Ex. 11 (D.I. 309), Nov. 19, 2012 Grooms Rep. at 61-62; Pfizer Ex. 13 (D.I. 309), Jan. 4, 2013 Grooms Rep. at 28; Ex. 32, Jan. 4, 2013 Leonard Rep. at 1. [redacted]

**ASSERTED FACT #259 RESPONSE:**

Pfizer incorporates by response its response to Bayer SOF 133. Pfizer further dispute the use of "long-acting." For example, Advocin can be considered long-acting. Pfizer Ex. 17 (D.I.

357), Clay Dep. at 64. There is no bright line between longer acting formulations and other formulations. Pfizer Ex. 12 (D.I. 309), Jan. 4, 2013 Babish Rep. ¶ 6. Ms. Elliott considers Advocin to be long acting relative to a daily injection product. Ex. 31, Elliott Dep. 37.

**ASSERTED FACT #260 RESPONSE:**

Pfizer incorporates by response its response to Bayer SOF 134. Pfizer further disputes the use of "long-acting." For example, Advocin can be considered long-acting. Pfizer Ex. 17 (D.I. 357), Clay Dep. at 64. There is no bright line between longer acting formulations and other formulations. Pfizer Ex. 12 (D.I. 309), Jan. 4, 2013 Babish Rep. ¶ 6. Ms. Elliott considers Advocin to be long acting relative to a daily injection product. Ex. 31, Elliott Dep. 37.

**ASSERTED FACT #261 RESPONSE:**

Pfizer incorporates by response its response to Bayer SOF 143. Pfizer further disputes the use of "long-acting." For example, Advocin can be considered long-acting. Pfizer Ex. 17 (D.I. 357), Clay Dep. at 64. There is no bright line between longer acting formulations and other formulations. Pfizer Ex. 12 (D.I. 309), Jan. 4, 2013 Babish Rep. ¶ 6. Ms. Elliott considers Advocin to be long acting relative to a daily injection product. Ex. 31, Elliott Dep. 37.

**ASSERTED FACT #262 RESPONSE:**

Pfizer objects to this Asserted Fact as vague and ambiguous, irrelevant and immaterial to Bayer's motion, and thus disputed. The key component of the vehicle used in LA-200, the "peak-only" formulation in the 93-052 study, and Advocin is the same. Pfizer SOF 32-37 re Non-infringement (D.I. 357). Additionally, some consider Advocin to include a long-acting formulation. Pfizer SOF 38, 39 re Non-infringement (D.I. 357); *see also* Ex. 31, Elliott Dep. 37.

**ASSERTED FACT #263 RESPONSE:**

Pfizer incorporates by response its response to Bayer SOF 144. [redacted]

[redacted]

Bayer Ex. 90 (D.I. 348) at 99-100.

The Pfizer 93-052 study occurred post-October 1993. Pfizer Ex. 28 (D.I. 309), PFE-BAY0001304. Dr. Giles testified that the Pfizer 93-052 study did not start until November 1993. Ex. 33, 6/13/12 Giles Dep. 97-98. [redacted]

**ASSERTED FACT #264 RESPONSE:**

Pfizer incorporates by response its response to Bayer SOF 145.

**ASSERTED FACT #265 RESPONSE:**

Pfizer incorporates by response its response to Bayer SOF 147.

**ASSERTED FACT #266 RESPONSE:**

Pfizer incorporates by response its response to Bayer SOF 148.

**ASSERTED FACT #267 RESPONSE:**

Pfizer incorporates by response its response to Bayer SOF 151.

**ASSERTED FACT #268 RESPONSE:**

Pfizer incorporates by response its response to Bayer SOF 152.

**ASSERTED FACT #269 RESPONSE:**

Pfizer incorporates by response its response to Bayer SOF 153. Pfizer further responds that Bayer's Ex. 108 makes no mention and has no connection to any study performed by Bayer and Bayer has not provided any evidence or arguments suggesting otherwise.

**ASSERTED FACT #270 RESPONSE:**

Pfizer incorporates by response its response to Bayer SOF 154.

**ASSERTED FACT #271 RESPONSE:**

Pfizer objects to this Asserted Fact as vague and ambiguous, irrelevant and immaterial to Bayer's motion, and thus disputed. For the same reasons that there is no nexus between any commercial success by Baytril 100 and the asserted claims, there is no nexus between any commercial success by Advocin and the asserted claims. *See e.g.*, Pfizer Ex. 10 (D.I. 309), Nov. 19, 2012 Babish Rep. ¶ 429; Pfizer Ex. 11 (D.I. 309), Nov. 19, 2012 Grooms Rep. at 61-62; Pfizer Ex. 13 (D.I. 309), Jan. 4, 2013 Grooms Rep. at 28; Ex. 32, Jan. 4, 2013 Leonard Rep. at 1. Pfizer incorporates by further response Pfizer Feb. 15, 2013 SOF 28-31 (D.I. 357).

**ASSERTED FACT #272 RESPONSE:**

Pfizer objects to this Asserted Fact as vague and ambiguous, irrelevant and immaterial to Bayer's motion, and thus disputed. Pfizer further disputes the asserted fact to the extent it suggests that Pfizer did not include the concentration dependent references in its invalidity contentions. *See e.g.*, Bayer Ex. 83 (D.I. 348) at Exhibit 2 (listing "Drusano, Meinen, Craig, Sullivan").

**ASSERTED FACT #273 RESPONSE:**

Pfizer objects to this Asserted Fact as vague and ambiguous, irrelevant and immaterial to Bayer's motion, and thus disputed. Pfizer identified which references anticipate the asserted claims. *See e.g.,* Bayer Ex. 83 (D.I. 348). Additionally, Pfizer has not taken any positions during expert discovery that are not sufficiently described in its invalidity contentions. Further, Local Patent Rule 2.3 does not require Pfizer to provide a reduction to practice date based on the Pfizer's 93-52 study. Regardless, the Pfizer 93-52 study was described in detail in Pfizer's claim chart for the Pfizer Prior Art Work. Ex. 34, Exhibit 1 to Pfizer's Nov. 16, 2012 Invalidity Contentions at 2-3.

**ASSERTED FACT #274 RESPONSE:**

Admitted.

**ASSERTED FACT #275 RESPONSE:**

Pfizer objects to this Asserted Fact as vague and ambiguous, irrelevant and immaterial to Bayer's motion, and thus disputed. [redacted]

Indeed, the '853 patent disclose a range of treatment options for treating BRD, including

a one high dose, single treatment. Pfizer Ex. 11 (D.I. 309), Nov. 19, 2012 Grooms Rep. at 34-36; *see also* Pfizer Ex. 9 (D.I. 309), '853 patent at 9:24-33. [redacted]

**ASSERTED FACT #276 RESPONSE:**

Pfizer objects to this Asserted Fact as irrelevant and immaterial to Bayer's motion, and thus disputed. The '853 patent discloses that, with respect to cattle suffering from BRD, a range of treatments are available, including a single dose treatment. Pfizer Ex. 9 (D.I. 309), '853 patent at 9:24-33; [redacted] Further, Bayer does not challenge the presumed enablement of the '853 patent. Also, Pfizer disputes that "the only cattle disease known to be treatable with a single dose before 1995 was E. Coli diarrhea." For example, the '979 patent describes treating BRD with a single dose of a fluoroquinolone and is prior art to the '506 patent. Pfizer Ex. 29 (D.I. 309), '979 patent at 4:38-46. Pfizer was working on and successfully reduced to practice a single dose danofloxacin treatment by 1993. D.I. 354, Pfizer SOF in Opp. to Bayer's Prior Invention Motion at SOF ¶¶ 201-207. Further, there were at least five single-dose treatments for BRD in June of 1995. Pfizer Ex. 15 (D.I. 309), Clay 1/24/2013 Dep. 46.

**ASSERTED FACT #277 RESPONSE:**

Pfizer objects to this Asserted Fact as vague and ambiguous, irrelevant and immaterial to Bayer's motion, and thus disputed. The '853 patent explicitly states "once to twice a day, for 1 to 15, preferably 1 to 5 days, where appropriate repeated." Included in this disclosure is once for one day. The '853 patent also does not qualify this once for one day treatment as not being applicable to shipping fever in cattle (i.e., BRD).

**ASSERTED FACT #278 RESPONSE:**

Pfizer objects to this Asserted Fact as vague and ambiguous, irrelevant and immaterial to Bayer's motion, and thus disputed. Dr. Babish and Dr. Clay explained in detail how the '853 patent anticipates the asserted claims. Pfizer Ex. 10 (D.I. 309), Nov. 19, 2012 Babish Rep. ¶¶ 210-222; Pfizer Ex. 11 (D.I. 309), Nov. 19, 2012 Grooms Rep. at 34-38; Pfizer Ex. 12 (D.I. 309), Jan. 4, 2013 Babish Rep. ¶¶ 61-66; Pfizer Ex. 13 (D.I. 309), Jan. 4, 2013 Grooms Rep. at 21-23.

[redacted], however that does not support Bayer's statement of fact that Pfizer's experts failed to explain how the '853 patent discloses each and every limitation of the claims.

**ASSERTED FACT #279 RESPONSE:**

Pfizer objects to this Asserted Fact as irrelevant and immaterial to Bayer's motion, and thus disputed.

**ASSERTED FACT #280 RESPONSE:**

Pfizer objects to this Asserted Fact as irrelevant and immaterial to Bayer's motion, and thus disputed. Pfizer further incorporates by reference its response to Bayer SOF 262 to note

that Advocin could be considered a long-acting formulation.

**ASSERTED FACT #281 RESPONSE:**

Pfizer incorporates by response its response to Bayer SOF 155. Pfizer's single dose danofloxacin work was also disclosed in Giles, Mann I and Mann II. [redacted]

**ASSERTED FACT #282 RESPONSE:**

Pfizer objects to this Asserted Fact as irrelevant and immaterial to Bayer's motion, and thus disputed. Pfizer is unable to understand the asserted fact because it is an incomplete sentence. Pfizer does not dispute that the words "extended duration" are written in the '979 patent. Pfizer further incorporates by reference its response to Bayer SOF 283.

**ASSERTED FACT #283 RESPONSE:**

Pfizer objects to this Asserted Fact as irrelevant and immaterial to Bayer's motion, and it is disputed. Dr. Babish only admitted that the questioning attorney read a sentence from the '979 patent correctly and what the abstract explicitly states, which is not the entirety of the prior art '979 patent's disclosure. *See, e.g. Leggett & Platt, Inc. v. VUTEk, Inc.*, 537 F.3d 1349, 1356 (Fed. Cir. 2008) (rejecting the "erroneous assumption that the disclosure of multiple examples [in a prior art reference] renders one example less anticipatory"); *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1376 (Fed. Cir. 2005) (rejecting argument that one example "cannot anticipate because it appears without special emphasis in a longer list"). Additionally, Dr. Babish and Dr. Grooms opine that the '979 patent does expressly disclose a one high dose, single treatment. Pfizer Ex. 10 (D.I. 309), Nov. 19, 2012 Babish Rep ¶¶ 226, 227; Pfizer Ex. 11 (D.I. 309), Nov. 19, 2012 Grooms Rep. at 30-31; Pfizer Ex 12 (D.I. 309), Jan. 4, 2013 Babish Rep. ¶¶ 67-71; Pfizer Ex 13 (D.I. 309), Jan. 4, 2013 Grooms Rep. at 18-20. For example the '979 patent

discloses a single dose treatment. Pfizer Ex. 29 (D.I. 348) at 4:39-42 ("it is preferred that the present method consist of orally administering an effective amount of the composition in a single dosage to a ruminant in need thereof")

**ASSERTED FACT #284 RESPONSE:**

Pfizer objects to this Asserted Fact as irrelevant and immaterial to Bayer's motion, and thus disputed. The single dose Dr. Grooms testified about with respect to dogs is not the only disclosure in the '160 patent of a single dose. *See e.g.* Pfizer Ex. 10 (D.I. 309), Nov. 19, 2012 Babish Rep ¶ 239; Pfizer Ex. 11 (D.I. 309), Nov. 19, 2012 Grooms Rep. at 39.

**ASSERTED FACT #285 RESPONSE:**

Pfizer objects to this Asserted Fact as irrelevant and immaterial to Bayer's motion, and thus disputed. Pfizer does not dispute that Dr. Grooms testified that the '160 patent does not expressly state "use of fluoroquinolone single dose for BRD." However, a verbatim statement of "use of fluoroquinolone single dose for BRD," "one high dose, single treatment" or "bovine respiratory disease" is not required in the '979 patent for it to disclose a one high dose, single treatment of BRD. Moreover, the '160 patent discloses each and every element of the claims. *See e.g.*, Pfizer Ex. 10 (D.I. 309), Nov. 19, 2012 Babish Rep ¶¶ 239-40; Pfizer Ex. 11(D.I. 309), Nov. 19, 2012 Grooms Rep at 39; Pfizer Ex. 12 (D.I. 309), Jan. 4, 2013 Babish Rep ¶¶ 72-75; Pfizer Ex. 13 (D.I. 309), Jan. 4, 2013 Grooms Rep at 23-24.

**ASSERTED FACT #286 RESPONSE:**

Pfizer objects to this Asserted Fact as irrelevant and immaterial to Bayer's motion, and thus disputed. Pfizer does not dispute that Column 3 of the Seki application does not disclose a BRD treatment because it discloses an eye infection treatment. However, Pfizer disputes that the Seki Application fails to disclose a single dose BRD treatment in Column 4. *See e.g.*, Pfizer Ex.

10 (D.I. 309), Nov. 19, 2012 Babish Rep ¶ 251; Pfizer Ex. 11 (D.I. 309), Nov. 19, 2012 Grooms Rep. at 40-42.

**ASSERTED FACT #287 RESPONSE:**

Pfizer objects to this Asserted Fact as vague and ambiguous, irrelevant and immaterial to Bayer's motion, and thus disputed. Dr. Grooms only testified that pharmacokinetic studies do not expressly disclose a treatment for BRD. Bayer Ex. 91 (D.I. 348) at 404:3-5. Dr. Giles testified that a dosing regimen is tested in Giles I. Bayer Ex. 90 (D.I. 348) at 43-44. Dr. Mann merely testified that Mann II does not disclose a disease model study. Bayer Ex. 112 (D.I. 348) at 62-64. Moreover, pharmacokinetic studies can be used to determine a method treating BRD. Pfizer Ex. 10 (D.I. 309), Nov. 19, 2012 Babish Rep ¶¶ 57-61; Pfizer Ex. 11 (D.I. 309), Nov. 19, 2012 Grooms Rep. at 43; Pfizer Ex 12 (D.I. 309), Jan. 4, 2013 Babish Rep. ¶¶ 35-39; Pfizer Ex 13 (D.I. 309), Jan. 4, 2013 Grooms Rep. at 16-17.

**ASSERTED FACT #288 RESPONSE:**

Pfizer objects to this Asserted Fact as vague and ambiguous, and thus disputed. Dr. Grooms testified that Drusano "recommend[s] … one-day treatments." Bayer Ex. 91 (D.I. 348) at 164. Dr. Babish only testified that Drusano does not provide data for a study of a single-dose treatment. Bayer Ex. 85 (D.I. 348) at 251-52. Dr. Babish also would not agree that Craig does not suggest a single-dose treatment. *Id.* at 265. With respect to Meinen, Dr. Babish only testified that Meinen does not provide data for a study of a single-dose treatment. *Id.* at 269-70. Dr. Babish made the same limited testimony with respect to Sullivan. *Id.* at 260. Drusano, Craig, Meinen, and Sullivan teach that fluoroquinolones are concentration dependent and

therefore provide an expectation of success in using a fluoroquinolone in a one high dose, single treatment. Pfizer Ex. 10 (D.I. 309), Nov. 19, 2012 Babish Rep ¶¶ 45-50; Pfizer Ex. 11 (D.I. 309), Nov. 19, 2012 Grooms Rep. at 49; Pfizer Ex 12 (D.I. 309), Jan. 4, 2013 Babish Rep. at 11-13; Pfizer Ex 13 (D.I. 309), Jan. 4, 2013 Grooms Rep. at 12-15.

**ASSERTED FACT #289 RESPONSE:**

Pfizer objects to this Asserted Fact as vague and ambiguous, and thus disputed. Gaunt, Backhouse, Kaplowitz, Moran, Morel and Siboulet are instructive to a person having ordinary skill in the art seeking a treatment for BRD. Pfizer Ex. 27 (D.I. 309), Papich Dep. Ex. 14 at 319; Pfizer Ex. 7 (D.I. 309), Papich Dep. 115-17; *see also* Pfizer Ex 12 (D.I. 309), Jan. 4, 2013 Babish Rep. ¶¶ 40-44; Pfizer Ex 13 (D.I. 309), Jan. 4, 2013 Grooms Rep. at 17-18. *See also* Pfizer SOF 75, 76.

**PFIZER'S ADDITIONAL STATEMENT OF MATERIAL FACTS**

73. U.S. Pat. No. 4,800,039 discloses a method of "reducing turbidity in aqueous systems," that includes "low-alkalinity systems (i.e., 150 ppm or less)" comprising two chemicals: (a) aluminum chlorohydrate; and (b) either a "water-soluble polyamines" or a "water-soluble dialkyl diallyl ammonium polymer[], wherein the weight ratio of (a) to (b) is at least 5:1, and preferably ranges from 10:1 to about 100:1…." The "water-soluble polyamines" option preferably has a molecular weight ranging from 10,000-150,000 and the "water-soluble dialkyl diallyl ammonium polymer" option preferably has a molecular weight from 1,000 to 5,000,000. Ex. 37, U.S. Pat. No. 4,800,039 at 2:20-3:6.

74. Dr. Clay was asked the following questions and provided the following answers:

> Q: Right. This is my one opportunity to find out where in the words of claims 4 or 5 you think there is a limitation that would exclude what you deem to be long-acting or sustained-release formulations. And so if you can tell me what words in the claims you would link to what you're referring to in the specification, please do so now.
>
> A: I can't point to a word there.
>
> Q: But your opinions you've provided on in particular invalidity in this case are premised on your understanding that the '506 patent claims exclude sustained-release or long-acting formulations?
>
> A: That is correct.
>
> Q: Would your overall opinion on invalidity change if I asked you to assume that the claims of the '506 patent do encompass long-acting or sustained-release formulations of a single-dose fluoroquinolone treatment of cattle with BRD?
>
> A: I'd have to assess that at the time.
>
> Q: You have not considered the question of whether the Claims 4 and 5 of the '506 patient are valid if we assume that sustained-release or long-acting formulations of fluoroquinolones are included within the scope of those claims?
>
> A: No, because I don't believe they're included.

Ex. 38, 1/24/13 Clay Dep. 60-61.

75. A person of ordinary skill in the art would look to treatment regimens that might have worked with other animals to bolster the expectation of success for treatment of cattle with BRD. Pfizer Ex 12 (D.I. 309), Jan. 4, 2013 Babish Rep. ¶¶ 40-44; Ex 13 (D.I. 309), Jan. 4, 2013 Grooms Rep. at 17-18.

76. The McGuirk 1992 reference states:

> Quinolone antibacterial agents continue to represent an important new class of therapeutically useful compounds….In recent years, several of these agents have been applied successfully in the treatment of a wide range of human bacterial infections. Less attention has been paid to their application in veterinary medicine. It seemed to us that a quinolone with suitable properties would be of considerable interest in this area, where the need for new therapy, particularly against resistant strains of primarily Gram-negative bacteria, is great.

Ex. 39, at PFE-BAY0000790-91

77. The Hornedo reference is a prior art reference that was the basis for an obviousness contention by Pfizer. Bayer Ex. 83 (D.I. 348) at 13; Pfizer Ex. 10 (D.I. 309), Nov. 19, 2012 Babish Rep ¶¶ 45-50; Pfizer Ex. 11 (D.I. 309), Nov. 19, 2012 Grooms Rep. at 53-56.

78. The Hornedo reference discloses single-dose enrofloxacin treatments (e.g., 2.5, 5.0 and 10 mg/kg in a single dose) to treat swine pneumonia that Pfizer's experts contend renders the asserted claims obvious. Pfizer Ex. 10 (D.I. 309), Nov. 19, 2012 Babish Rep ¶¶ 389-399; Pfizer Ex. 11 (D.I. 309), Nov. 19, 2012 Grooms Rep. at 53-56.; Ex. 40, Hornedo reference.

79. Giles I, Mann I and Mann II are all anticipatory references, as well as references that render asserted claims obvious. *See* Pfizer Ex. 10 (D.I. 309), Nov. 19, 2012 Babish Rep ¶¶ 260-299 (Giles I, Mann I, Mann II); Pfizer Ex. 11 (D.I. 309), Nov. 19, 2012 Grooms Rep at 32-34 (Mann II), 42-49 (Mann I, Giles I).

80. Pharmacology studies such as Giles I, Mann I and Mann II can describe and suggest methods of treating BRD. *See* Pfizer Ex. 12 (D.I. 309), Jan. 4, 2013 Babish Rep ¶¶ 35-39; Pfizer Ex. 13 (D.I.), Jan. 4, 2013 Grooms Rep at 16-17.

[redacted]

82. Dr. Babish and Dr. Grooms provided at least 41 pages laying out the obviousness combinations that are not based on the '853 patent, the '979 patent, the '160 patent, the Seki Publication, Giles I, Mann I or Mann II. Pfizer Ex. 10 (D.I. 309), Nov. 19, 2012 Babish Rep at 121-204; Pfizer Ex. 11 (D.I. 309), Nov. 19, 2012 Grooms Rep. at 49-61.

[redacted]

[redacted]

85. Pfizer contends that the '853 patent is obvious in view of Gaunt, Backhouse, Moran, Kaplowitz, Siboulet, Hornedo or Gorham. *See e.g.,* Pfizer Ex. 10 (D.I. 309), Nov. 19, 2012 Babish Rep. ¶¶ 219-221; Bayer Ex. 83 (D.I. 348) at Exhibit 2 ('853 patent claim chart).

Dated: February 22, 2013

*/s/ Marcus E. Sernel, P.C.*

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**CERTIFICATE OF SERVICE**

I hereby certify that on February 22, 2013, a true and correct copy of the foregoing document, **PFIZER INC.'S RESPONSES TO BAYER'S STATEMENT OF MATERIAL FACTS IN SUPPORT OF ITS MOTION FOR PARTIAL SUMMARY JUDGMENT DISMISSING PFIZER'S ANTICIPATION AND OBVIOUSNESS DEFENSES**, was served via ECF on the following counsel of record:

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